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COMPREHENSIVE SMOKELESS TOBACCO AND HEALTH EDUCATION ACT OF 1985

DECEMBER 4 (legislative day, DECEMBER 2), 1985.—Ordered to be printed

Mr. HATCH, from the Committee on Labor and Human Resources, submitted the following

REPORT

[To accompany S. 1574]

The Committee on Labor and Human Resources, to which was referred the bill (S. 1574) to provide for public education concerning the health consequences of using smokeless tobacco products, having considered the same, reports favorably thereon with an amendment in the nature of a substitute and recommends that the bill as amended do pass.

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I. SUMMARY OF THE BILL

As reported by the Committee, S. 1574 would direct the Secretary of Health and Human Services to establish a program to inform the public of any changes to human health associated with the use of smokeless tobacco products. The Secretary is directed to develop educational programs and materials and public service announcements on the dangers to human health from the use of smokeless tobacco and make appropriate programs, materials, and announce-

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ments available to States, local governments, school systems, and other entities. The Secretary is also directed to conduct and support research on the effects of smokeless tobacco on human health and to collect, analyze, and disseminate information and studies on smokeless tobacco and health.

The Secretary would be authorized to provide technical assistance to States to assist them in developing educatioanal programs and materials and public service announcements on the dangers to human health from the use of smokeless tobacco.

The bill would direct the Secretary to transmit a report to the Congress not later than January 1, 1987, and biennially thereafter. The report would contain: (1) a description of the effects oif health education efforts on the use of smokeless tobacco products; (2) a description of the public use of smokeless tobacco products; (3) an evaluation of the health effects of smokeless tobacco products and an identification of areas for further research; and (4) recommendations for appropriate legislation and administrative action.

S. 1574 would require the display of one of three warning statements on smokeless tobacco product packages and smokeless tobacco advertising:

> WARNING: THIS PRODUCT MAY CAUSE MOUTH CANCER;
>
> WARNING: THIS PRODUCT MAY CAUSE GUM DISEASE AND TOOTH LOSS; AND
>
> WARNING: THIS PRODUCT IS NOT A SAFE ALTERNATIVE TO CIGARETTES.

The statements would be randomly displayed on each package of smokeless tobacco product by a manufacturer, packager, or importer of a smokeless tobacco product in each twelve-month period in as equal number of times as possible and would be randomly distributed in all parts of the United States in which the product is marketed. The labels would be displayed and distributed in accordance with the regulations and guidelines issued by the FTC pursuant to a plan submitted to and approved by the FTC.

Each of the three warning statements would be rotated every four months in advertisements for each brand of smokeless tobacco products, in accordance with the regulations and guidelines issued by the FTC pursuant to a play submitted to and approved by the FTC. In the case of a radio or television advertisement for a smokeless tobacco product, one of the statements would have to be read once during the advertisement in compliance with FTC guidelines.

The bill would require the FTC to promulgate and periodically revise regulations and guidelines to implement the warning statement and advertising provisions of the bill. Within 180 days of the enactment of the bill, the FTC would be required to promulgate guidelines regarding the display, format and distribution of the statements required on smokeless tobacco packages and the rotation, display, format, and distribution of the statements on each advertisement.

The bill would establish a smokeless tobacco "additive" reporting system. Each person who manufactures, packages, or imports smokeless tobacco products would have to provide the Secretary of HHS annually with a list of ingredients added to tobacco in the

manufacture of the product and a specification of the quantity of nicotine contained in each product. The ingredient list would not the FTC, recommend to the Congress appropriate revisions to the warning statements contained in this legislation.

II. BACKGROUND AND NEED FOR LEGISLATION

Over the past twenty years, the Congress and the Federal Government have taken a strong stand on the hazards to human health of cigarette smoking. Nearly neglected in this history of concern and action has been the use of smokeless tobacco products, such as snuff and chewing tobacco, and the hazards of such use to health. The smokeless tobacco industry, once almost the forgotten factor in tobacco production and sales, has staged a resurgence in recent years. Estimated from the National Institutes of Health indicate that some 22 million Americans currently use smokeless tobacco products regularly.

The evidence has steadily mounted on the health risks of smokeless tobacco use. Gains in production and sales of such products over the past ten years have made it essential that Congress and the Federal Government take action to broaden our knowledge on effects of smokeless tobacco use and to make such knowledge readily available to the public. The apparent popularity of smokeless tobacco among our children and youth make such legislative action particularly crucial.

The various types of smokeless tobacco, such as chewing tobacco and snuff, contain, like tobacco that is smoked, significant levels of nicotine. Nicotine use in the levels found in smokeless tobacco has been associated with a rise in blood pressure, and may increase the risk of addiction. In addition, the use of smokeless tobacco products has been strongly associated with certain alterations in the tissues of the mouth, such as gingival recession (recession of the gums), periodontal bone destruction, and tooth abrasion. Most importantly, perhaps, smokeless tobacco use has been linked to the development of precancerous lesions, such as leukoplakia. Approximately 7 percent of leukoplakia lesions convert to squamous cell carcinomas accounting for roughly 90 percent of all oral cancers.

One study indicates that the risk of developing cancer is four times greater for users of snuff than for nonusers, and approaches 50 times greater for chronic long-term users. Another group has reported research that there may be as many as 700 deaths per year from oral cancer caused by smokeless tobacco use. The Surgeon General of the United States has reported that smokeless tobacco contains the highest amount of certain cancer-causing toxins in a consumer product for oral consumption, and, in a letter to the Federal Trade Commission in December of 1984, stated that "Smokeless tobacco including snuff does indeed pose a cancer threat and is associated as well with certain other pathologic oral conditions."

Until fairly recently, the use of smokeless tobacco in the U.S. had been restricted to a relatively small percentage of the population and had declined in volume of sale and use from the early years of this century. The 1964 Surgeon General's report on smoking and health, which barely mentions smokeless tobacco products, includes a table (page 45) showing consumption of tobacco products

for selected years between 1900 and 1962. The table shows the insignificance of smokeless tobacco use in the early 1960s compared with earlier days. While cigarette consumption had risen from 49 cigarettes per person in 1900 to 3,958 per person in 1962, consumption of chewing tobacco had fallen from 4.10 pounds per person to 0.50 pounds per person during the same period. Consumption of snuff declined slightly from 0.32 pounds per person in 1900 to 0.26 pounds per person in 1962. The decline continued into the 1970s. By 1974 the annual per capita consumption of snuff had dropped to .18 pounds per person.

There has been resurgence in recent years, in the popularity of smokeless tobacco products, particularly snuff. According to Standard and Poor's Industry Survey of April 1985, moist snuff is the fastest-growing product in the entire tobacco industry, with poundage gains of 7 percent in 1984. Annual per capita consumption is back up to .26 pounds for 1983.

One of the sources of concern about the increase in the use of smokeless tobacco products and a major reason for the development of a legislative proposal is the alarming incidence of use by children. Studies have shown that almost 10 percent of high school students regularly use smokeless tobacco products. A recent study of persons who regularly use such products indicated that 88 percent started using smokeless tobacco before the age of 15 and 55 percent started before the age of 13.

Apparently many of these young people are under the mistaken impression that the use of smokeless tobacco carries no significant risk to health. The 1964 Surgeon General's report on cigarettes and health with the subsequent legislation to require warning labels and limit advertising have established a public awareness of the dangers of cigarette smoking. There has been no parallel development of public information on the dangers of smokeless tobacco use. Young people starting to use such products, perhaps as hopeful symbols of maturity, seem to view smokeless tobacco as a safe and healthful alternative to cigarettes. Current packaging and promotional practices, including endorsement by professional athletes, further this mistaken impression.

The significant health risks associated with smokeless tobacco use, the public's seeming lack of awareness about such risks, and the popularity of the product among children and adolescents have led to concern and action on various fronts. A number of national health and professional organizations, such as the American Cancer Society, the American Lung Association, the American Heart Association, the American Dental Association, the American Academy of Otolaryngology, the American Association of Pediatrics, and the American Medical Association, have called for the enactment of legislation to require warning labels on smokeless tobacco products and in advertisements. Massachusetts has required, by executive order, that every package of moist snuff sold in the State after December 1, 1985, carry a warning label. Other States are considering similar action.

Early in 1985, the Health Research Group petitioned the Federal Trade Commission seeking warning label requirements for smokeless tobacco products. To assist in its considerations of the petition, the FTC requested information from the Surgeon General of the

U.S. In June 1985, in order to assist in this response to the FTC, the Surgeon General appointed an Advisory Committee on the Health Consequences of Using Smokeless Tobacco to study the issue. In addition, the National Cancer Institute, the National Institute of Dental Research, and the Office of Medical Applications of Research, National Institutes of Health are jointly sponsoring a consensus development conference in January of 1986 on the health implications of smokeless tobacco use.

III. HEARINGS

The Committee has a long-standing interest in the risks to human health of tobacco use and the importance of disease prevention and health promotion as important components of our national health policy. S. 1574, for the most part, simply extends the provisions of P.L. 98-474, the Comprehensive Smoking Education Act of 1984, to include smokeless tobacco products. The Committee held two days of hearings in May 1983 on the subject of education and research on smoking and health and related issues. These hearings including the issues of rotating warning statements on packages and in advertisements and the reporting to the Secretary of HHS of chemical additives, subjects dealt with in provisions of S. 1574. The Committee's interest in disease prevention and health promotion is further exemplified by hearings in April 1983 on the role of the Federal Government in these areas.

The Committee considered S. 1574 in executive session on November 19, 1985, and agreed to favorably report, without amendment, the Committee Substitute to the Senate.

IV. TEXT OF S. 1574 AS REPORTED

A BILL To provide for public education concerning the health consequences of using smokeless tobacco products

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled, ~~That this Act may be cited as the "Comprehensive Smokeless Tobacco and Health Education Act of 1985".~~

~~FINDINGS~~

~~SEC. 2. The Congress finds that—~~

~~(1) scientific research has determined that—~~

~~(A) the use of smokeless tobacco is a cause of oral and pharyngeal cancer, oral leukoplakia, gum disease, and tooth loss; and~~

~~(B) smokeless tobacco contains nicotine and may be addictive;~~

~~(2) the use of smokeless tobacco by adolescents is increasing;~~

~~(3) there is a widespread lack of knowledge among the general public of the health risks associated with the use of smokeless tobacco; and~~

~~(4) State and local efforts are insufficient to educate the public on the dangers of smokeless tobacco use.~~

~~PUBLIC EDUCATION~~

~~SEC. 3. (a)(1) The Secretary of Health and Human Services, through the Office of Smoking and Health of the Department of Health and Human Services, shall—~~

(A) develop educational programs and materials and public service announcements respecting the dangers to human health from the use of smokeless tobacco; and

(B) make such programs, materials, and announcements available to States, local governments, and school systems.

(2) In developing programs, materials, and announcements under paragraph (1), the Secretary shall consult with the Secretary of Education, medical and public health entities, consumer groups, and other appropriate entities.

(b) One year after the date of the enactment of this Act, and annually thereafter, the Secretary shall transmit a report to the Congress concerning the activities undertaken under subsection (a) during the preceding year.

(c) The Secretary, through the Office of Smoking and Health of the Department of Health and Human Services, may provide technical assistance to States to assist such States in the development of educational programs and materials and public service announcements respecting the dangers to human health from the use of smokeless tobacco.

REPORT ON SMOKELESS TOBACCO AND HEALTH

SEC. 4. The Secretary, through the Surgeon General of the United States, shall transmit a report to the Congress not later than January 1, 1987, and annually thereafter, containing—

(1) a description of the effects of health education efforts on the use of smokeless tobacco products;

(2) a description of current practices and methods of smokeless tobacco product advertising and promotion;

(3) a description of the use by the public of smokeless tobacco products;

(4) an evaluation of the known health effects of smokeless tobacco products; and

(5) such recommendations for legislation and administrative action as the Secretary considers appropriate.

SMOKELESS TOBACCO WARNING STATEMENTS

SEC. 5. (a)(1) It shall be unlawful for any person to manufacture, package, or import for sale or distribution within the United States any smokeless tobacco product unless the package of the product bears, in accordance with the requirements of this section, one of the following statements:

"WARNING: THIS PRODUCT MAY CAUSE MOUTH CANCER

"WARNING: THIS PRODUCT MAY CAUSE GUM DISEASE AND TOOTH LOSS

"WARNING: THIS PRODUCT CONTAINS NICOTINE AND MAY BE ADDICTIVE".

(2) It shall be unlawful for any manufacturer or importer of a smokeless tobacco product to advertise or cause to be advertised within the United States any smokeless tobacco product unless—

(A) the advertising of such product bears one of the statements specified in paragraph (1);

(B) in the case of television advertising, one of the statements specified in paragraph (1)—

(i) appears for the duration of each advertisement; or

(ii) is read once during each advertisement; and

(C) in the case of radio advertising, one of the statements specified in paragraph (1) is read once during each advertisement.

(b) Each statement required by subsection (a) shall appear—

(1) in the case of the smokeless tobacco product package—

(A) on the top of the package or in another prominent location on the package; and

(B) in conspicuous and legible type in contrast by typography, layout, and color with all other printed material on the package; and

(2) in the case of print and television advertising—

(A) in a conspicuous location and in conspicuous and legible type in contrast by typography, layout, and color with all other printed material in the advertisement; and

(B) in a format prescribed by the Federal Trade Commission.

(c) The statements specified in paragraph (1) of subsection (a) shall be rotated by each manufacturer or importer of a smokeless tobacco product in each twelve-month period in an alternating sequence on packages of each brand of smokeless tobacco product manufactured by the manufacturer or importer and in the advertisements for each such brand of smokeless tobacco product in accordance with a plan submitted by the manufacturer or importer and approved by the Federal Trade Commission. The Federal Trade Commission shall approve a plan submitted by a manufacturer or importer of a smokeless tobacco product which will provide the rotation required by this subsection and which assures that all of the statements required by paragraph (1) of subsection (a) will be displayed by the manufacturer or importer at the same time.

(d) Not later than 180 days after the date of enactment of this Act, the Federal Trade Commission shall promulgate such regulations as it may require to implement subsections (a), (b), and (c).

(e)(1) After the Advisory Committee on the Health Consequences of Using Smokeless Tobacco appointed by the Surgeon General of the United States completes its study and report concerning the health consequences of using smokeless tobacco products, the Surgeon General and the Federal Trade Commission shall review the findings and conclusions of such study. After the completion of such review, the Federal Trade Commission may, by regulation, promulgate revisions of the statements specified in paragraph (1) of subsection (a). Any such revision shall be based on the findings and conclusions of such study.

(2) Any regulations promulgated under paragraph (1) of this subsection shall be promulgated in accordance with subchapter II of chapter 5 of title 5, United States Code.

(f) Any person who violates the provisions of this section shall be guilty of a misdemeanor and shall on conviction thereof be subject to a fine of not more than $10,000.

(g) The several district courts of the United States are invested with jurisdiction, for cause shown, to prevent and restrain violations of this section upon application of the Attorney General of the United States acting through the several United States attorneys in their several districts.

(h)(1) No statement relating to the use of smokeless tobacco products and health, other than the statements required by this section, shall be required on any package of a smokeless tobacco product.

(2) No requirement or prohibition based on the use of smokeless tobacco products and health shall be imposed under State law with respect to the advertising or promotion of any smokeless tobacco product the packages of which are labeled, and the advertisement of which is conducted, in conformity with the provisions of this section.

~~DEFINITIONS~~

~~SEC. 6. For purposes of this Act—~~

~~(1) the term "package" means a pack, box, carton, can, or any other container of any kind in which smokeless tobacco is offered for sale, sold, or otherwise distributed to consumers;~~

~~(2) the term "person" has the same meaning as in section 3(a) of the Federal Cigarette Labeling and Advertising Act;~~

~~(3) the term "Secretary" means the Secretary of Health and Human Services;~~

~~(4) the term "smokeless tobacco" means any finely cut, ground, powdered, or leaf tobacco that is intended to be placed in the oral cavity; and~~

~~(5) the term "United States" has the same meaning as in section 3(3) of such Act.~~

~~EFFECTIVE DATE~~

~~SEC. 7. (a) Except as provided in subsection (b), this Act shall take effect one year after the date of enactment of this Act.~~

~~(b) Section 5(d) shall take effect on the date of enactment of this Act.~~

That this Act may be cited as the "Comprehensive Smokeless Tobacco and Health Education Act of 1985".

PUBLIC EDUCATION

SEC. 2. (a)(1) The Secretary of Health and Human Services shall establish and carry out a program to inform the public of any changes to human health resulting from the use of smokeless tobacco products. In carrying out such program, the Secretary shall—

(A) develop educational programs and materials and public service announcements respecting the dangers to human health from the use of smokeless tobacco;

(B) make such programs, materials, and announcements available to States, local governments, school systems, and such other entities as the Secretary determines appropriate to further the purposes of this Act;

(C) conduct and support research on the effect of smokeless tobacco on human health; and

(D) collect, analyze, and disseminate information and studies on smokeless tobacco and health.

(2) In developing programs, materials, and announcements under paragraph (1), the Secretary shall consult with the Secretary of Education, medical and public health entities, consumer groups, representatives of manufacturers of smokeless tobacco products, and other appropriate entities.

(b) The Secretary may provide technical assistance to States to assist such States in the development of educational programs and materials and public service announcements respecting the dangers to human health from the use of smokeless tobacco.

REPORT ON SMOKELESS TOBACCO AND HEALTH

SEC. 3. The Secretary shall transmit a report to the Congress not later than January 1, 1987, and biennially thereafter, containing—

(1) a description of the effects of health education efforts on the use of smokeless tobacco products;

(2) a description of the use by the public of smokeless tobacco products;

(3) an evaluation of the health effects of smokeless tobacco products and an identification of areas appropriate for further research; and

(4) such recommendations for legislation and administrative action as the Secretary considers appropriate.

SMOKELESS TOBACCO PRODUCTS PACKAGES

SEC. 4. (a) It shall be unlawful for any person to knowingly manufacture, package, or import for sale or distribution within the United States any smokeless tobacco product unless the package of the product bears, in accordance with the requirements of this Act, one of the following statements:

"WARNING: THIS PRODUCT MAY CAUSE MOUTH CANCER

"WARNING: THIS PRODUCT MAY CAUSE GUM DISEASE AND TOOTH LOSS

"WARNING: THIS PRODUCT IS NOT A SAFE ALTERNATIVE TO CIGARETTES".

(b) One of the statements required by subsection (a) shall appear in a conspicuous and prominent location on each package of a smokeless tobacco product, and shall appear in a conspicuous format and in conspicuous and legible type in contrast with all other printed material on the package.

(c) The statements required by subsection (a) shall—

(1) be randomly displayed by a manufacturer, packager, or importer of a smokeless tobacco product in each twelve-month period in as equal a number of times as is possible; and

(2) be randomly distributed in all parts of the United States in which such product is marketed.

(d)(1) Each manufacturer, packager, or importer of a smokeless tobacco product shall submit a plan to the Federal Trade Commission which specifies the method such manufacturer, packager, or importer will use to display and distribute the statements required by subsection (a) in accordance with the requirements of subsections (b) and (c).

(2) The Federal Trade Commission shall approve a plan submitted by a manufacturer, packager, or importer of a smokeless tobacco product under paragraph (1) if such plan provides for the display and distribution on smokeless tobacco product packages of the statements required by subsection (a) in a manner which complies with this Act and the guidelines promulgated under section 6.

(e) This section and section 5 do not apply to a distributor or a retailer of any smokeless tobacco product which does not manufacture, package, or import smokeless tobacco products for sale or distribution within the United States.

ADVERTISING OF SMOKELESS TOBACCO PRODUCTS

SEC. 5. (a) It shall be unlawful for any manufacturer, packager, or importer of a smokeless tobacco product to knowingly advertise or cause to be advertised in the United States such smokeless tobacco

product unless such advertisement bears, in accordance with this section, one of the statements specified in section 4(a).

(b) Each statement specified in section 4(a) shall be rotated every four months by the manufacturer, packager, or importer of smokeless tobacco products in an alternating sequence in the advertisements for each brand of a smokeless tobacco product, in accordance with a method prescribed by the Federal Trade Commission.

(c)(1) In the case of a printed advertisement of a smokeless tobacco product, one of the statements specified in section 4(a) shall appear on such advertisement in a conspicuous and prominent location and a conspicuous format approved by the Federal Trade Commission, and in conspicuous and legible type in contrast with all other printed material in the advertisement.

(2) In the case of a radio or television advertisement of a smokeless tobacco product, one of the statements specified in section 4(a) shall be read once during the advertisement.

(d)(1) Each manufacturer, packager, or importer of a smokeless tobacco product shall submit a plan to the Federal Trade Commission which specifies the method such manufacturer, packager, or importer will use to rotate, display, and distribute in accordance with this Act the statements specified by section 4(a) in advertisements of smokeless tobacco products.

(2) The Federal Trade Commission shall approve a plan submitted by a manufacturer, packager, or importer of a smokeless tobacco product under paragraph (1) if such plan provides for the rotation, display, and distribution of the statements specified in section 4(a) on each advertisement of a smokeless tobacco product in a manner which complies with this Act and the guidelines promulgated under section 6.

REGULATIONS AND GUIDELINES

SEC. 6. (a) The Federal Trade Commission shall promulgate and periodically revise such regulations and guidelines as it may require to implement sections 4 and 5.

(b) Within 180 days after the date of enactment of this Act, the Federal Trade Commission shall promulgate guidelines with respect to—

(1) the display and distribution of the statements required by section 4(a) on packages of smokeless tobacco products; and

(2) the rotation, display, and distribution of the statements specified in section 4(a) on each advertisement of a smokeless tobacco product.

INGREDIENT REPORTING

SEC. 7. (a)(1) Each person who manufactures, packages, or imports smokeless tobacco products shall annually provide the Secretary with—

(A) a list of the ingredients added to tobacco in the manufacture of such products which does not identify the company which uses the ingredients or the brand of smokeless tobacco which contain the ingredients; and

(B) a specification of the quantity of nicotine contained in each such product.

(2) A person or group of persons required to provide information by this subsection may designate an individual or entity to provide the information required by this subsection.

(b)(1) At such times as the Secretary considers appropriate, the Secretary shall transmit to the Congress a report, based on the information provided under subsection (a), respecting—

(A) a summary of research activities and proposed research activities on the health effects of ingredients added to tobacco in the manufacture of smokeless tobacco products and the findings of such research;

(B) information pertaining to any such ingredient which in the judgment of the Secretary poses a health risk to users of smokeless tobacco; and

(C) any other information which the Secretary determines to be in the public interest.

(2)(A) Any information provided to the Secretary under subsection (a) shall be treated as trade secret or confidential information subject to section 552(b)(4) of title 5, United States Code, and section 1905 of title 18, United States Code, and shall not be revealed, except as provided in paragraph (1), to any person other than those authorized by the Secretary in carrying out their official duties under this section.

(B) Subparagraph (A) does not authorize the withholding of information provided under subsection (a) of this section from any duly authorized subcommittee or committee of the Congress. If a subcommittee or committee of the Congress requests the Secretary to provide it such information, the Secretary shall make the information available to the subcommittee or committee and shall, at the same time, notify in writing the person who provided the information of such request.

(C) The Secretary shall establish written procedures to assure the confidentiality of information provided under subsection (a) of this section. Such procedures shall include the designation of a duly authorized agent to serve as custodian of such information. The agent—

(i) shall take physical possession of the information and, when not in use by a person authorized to have access to such information, shall store it in a locked cabinet or file; and

(ii) shall maintain a complete record of any person who inspects or uses the information.

Such procedures shall require that any person permitted access to the information shall be instructed in writing not to disclose the information to anyone who is not entitled to have access to the information.

PENALTY

SEC. 8. Any person who is found to violate any provision of this Act shall be guilty of a misdemeanor and shall on conviction thereof be subject to a fine of not more than $10,000.

ENFORCEMENT

SEC. 9. The several district courts of the United States are invested with jurisdiction, for cause shown, to prevent and restrain viola-

tions of this Act upon application of the Federal Trade Commission or upon application of the Attorney General of the United States acting through the several United States attorneys in their several districts.

PREEMPTION

SEC. 10. (a) No statement relating to the use of smokeless tobacco products and health, other than the statements required by this Act, shall be required by any Federal agency to appear on any package or in any advertisement of a smokeless tobacco product.

(b) No statement relating to the use of smokeless tobacco products and health, other than the statements required by this Act, shall be required by any State or local law or regulation to be included on any package or in any advertisement of a smokeless tobacco product.

STUDY AND RECOMMENDATIONS

SEC. 11. After the Advisory Committee on the Health Consequences of Using Smokeless Tobacco appointed by the Surgeon General of the United States completes its study and report concerning the health consequences of using smokeless tobacco products, the Surgeon General shall review the findings and conclusions of such study. After the completion of such review, the Surgeon General, in consultation with the Federal Trade Commission, shall recommend to the Congress appropriate revisions to the statements specified in section 4(a). Any such recommendations shall be based on the findings and conclusions of such study.

DEFINITIONS

SEC. 12. For purposes of this Act—

(1) the term "package" means a pack, box, carton, can, or any other container of any kind in which smokeless tobacco is offered for sale, sold, or otherwise distributed to consumers;

(2) the term "person" has the same meaning as in section 3(5) of the Federal Cigarette Labeling and Advertising Act;

(3) the term "Secretary" means the Secretary of Health and Human Services;

(4) the term "smokeless tobacco" means any finely cut, ground, powdered, or leaf tobacco that is intended to be placed in the oral cavity; and

(5) the term "United States" has the same meaning as in section 3(3) of such Act.

EFFECTIVE DATE

SEC. 13. (a) Except as provided in subsection (b), this Act shall take effect one year after the date of enactment of this Act.

(b) Sections 2, 3, 4(d), 5(d), and 6 shall take effect on the date of enactment of this Act.

V. COMMITTEE VIEWS

The Committee reports S. 1574 as a timely and necessary measure to facilitate a national public education and research effort to make our citizens more aware of the health consequences of using

smokeless tobacco. This legislation has particular importance and urgency because of the apparent popularity of smokeless tobacco products among children and adolescents. It is essential that we inform the public of the health effects of smokeless tobacco use and we continue research on such health effects as expeditiously as possible.

The Committee wants to stress that it does not impose these requirements lightly. Tobacco products are unique in that, unlike other products which may be only hazardous when misused, these products pose a health hazard when used as intended.

The Committee does not deem this legislation as regulatory, nor proscriptive of our citizens' right to use smokeless tobacco, but simply as an appropriate and necessary Federal effort to provide for public education and research. The Committee considers this measure an important part of the ongoing effort in disease prevention and health promotion which is among the highest priorities of our national health policy.

The Federal Trade Commission will promulgate guidelines which describe the size and shape of the format and the size, type, layout, and color of the warnings statements and the background on which they appear. The primary concern for the Federal Trade Commission in developing guidelines for the format and for the display of the required statements on smokeless tobacco packages and in advertisements should be the effectiveness of the warning. The Federal Trade Commission may also consider the effect of the format on the message of the advertisement. The Federal Trade Commission, if it so chooses, may promulgate rules, rather than guidelines. The Federal Trade Commission shall be obligated to approve committee views.

The Committee reports S. 1574 as a timely and necessary measure to facilitate a national public education and research effort to make our citizens more aware of the health consequences of using smokeless tobacco. This legislation has particular importance and urgency because of the apparent popularity of smokeless tobacco products among children and adolescents. It is essential that we inform the public of the health effects of smokeless tobacco use and we continue research on such health effects as expeditiously as possible.

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Manufacturers, packagers, and importers need not be limited to the three warning statements included in this bill. They may, if they wish, add additional health warning information.

The Committee wants to make clear that manufacturers, packagers, and importers of smokeless tobacco products may submit their plans as required in sections 4 and 5 of this bill describing their proposed methods for displaying the statements on packages and in advertisements at any time after the bill's enactment into law. Manufacturers, packagers, and importers of smokeless tobacco products are not required to submit a plan upon enactment of this legislation. They are only required to have the health warnings on packages and advertisements under a plan approved by the Federal Trade Commission, one year after the date of the enactment.

The Committee has included in S. 1574 provisions requiring manufacturers, packagers, and importers of smokeless tobacco products to provide the Secretary of HHS annually with a list of ingredients added to tobacco in the manufacturing of smokeless tobacco products. This provision is similar to one in the 1984 Comprehensive Smoking Education Act, P.L. 98-474. It is included to further the accumulation of knowledge about the health risks of smokeless tobacco use, particularly the possible hazards of substances added to tobacco to enhance flavor and for other purposes. The bill also requires the reporting to the Secretary of HHS of the quantity of nicotine contained in each smokeless tobacco product.

The Committee, in provisions of S. 1574 which describe the responsibilities of the Federal Commission to administer the warning statements and advertising requirements of this legislation, has no intent to limit already existing powers of the Commission in the regulation of the advertising or sale of tobacco products.

Finally, the Committee wants to emphasize that, by including provisions in S. 1574 which require health warnings on packages and advertisements for smokeless tobacco products, and by preempting State and local laws requiring additional health warnings, it does not intend to preempt a State's ability to control the promotion or advertising of tobacco products and does not intend to preempt product liability suits in State or Federal courts based on failure to warn.

VI. VOTES IN COMMITTEE

Pursuant to section 133(b) of the Legislative Reorganization Act of 1946, the following is a tabulation of votes in committee:

The Committee on Labor and Human Resources voted, without objection, to favorably report S. 1574 with an amendment in the

nature of a substitute; and recommended that the bill as amended do pass.

VII. BUDGET ESTIMATE

U.S. CONGRESS,
CONGRESSIONAL BUDGET OFFICE,
Washington, DC, November 20, 1985.

Hon. ORRIN G. HATCH,
Chairman, Committee on Labor and Human Resources,
U.S. Senate, Washington, DC.

DEAR MR. CHAIRMAN: The Congressional Budget Office has prepared the attached cost estimate for S. 1574, the Comprehensive Smokeless Tobacco and Health Education Act of 1985, as ordered reported by the Senate Committee on Labor and Human Resources on November 19, 1985.

If you wish further details on this estimate, we will be pleased to provide them.

With best wishes,
Sincerely,

RUDOLPH R. PENNER.

CONGRESSIONAL BUDGET OFFICE—COST ESTIMATE

1. Bill number: S. 1574.
2. Bill title: Comprehensive Smokeless Tobacco and Health Education Act of 1985.
3. Bill status: As ordered reported by the Senate Committee on Labor and Human Resources on November 19, 1985.
4. Bill purpose: To provide for public education concerning the health consequences of using smokeless tobacco products.
5. Estimated cost to the Federal Government:

[By fiscal years, in millions of dollars]

	1986	1987	1988	1989	1990
Estimated authorization level	4.0	4.2	4.4	4.6	4.9
Estimated outlays	2.3	3.3	4.1	4.4	4.7

Basis of estimate: This bill would require the Secretary of Health and Human Services (HHS) to develop and distribute educational materials concerning the dangers of smokeless tobacco, and authorize technical assistance to states to do the same. The bill would also authorize research on the effect of smokeless tobacco on health. Smokeless tobacco manufacturers would be required to label their products and advertisements with one of three specific health warnings and to annually provide the Secretary of HHS with a list of ingredients and nicotine content for their products.

All of the costs associated with container labeling and ingredient reporting would be incurred by the tobacco manufacturer. Cost to the federal government would result from the federal initiative and the technical assistance provided to states to educate consumers on the dangers of smokeless tobacco and from smokeless tobacco re-

search. No specific funding level is authorized in the bill for these provisions. However, similar educational activities relating to cigarette smoking are conducted by the Smoking and Health program within the Public Health Service. This program received $3.5 million in 1985. The National Cancer Institute is doing research on the behavorial aspects of smokeless tobacco, funded at about $0.3 million. They are not, however, currently conducting research on the effects of smokeless tobacco on health, as described in the bill. We estimate that an appropriation level comparable to these would be necessary to carry out the provisions of S. 1574 relating to education and health research activities. The amount needed could be higher or lower depending on the actual level of activity.

We assume the estimated authorization amounts are fully appropriated at the beginning of each fiscal year. Outlays are estimated using spendout rates computed by CBO on the basis of recent program data.

6. Estimated cost to state and local government: The budgets of state and local governments would not be affected directly by the enactment of this bill.

7. Estimate comparison: None.

8. Previous CBO estimate: None.

9. Estimate prepared by: Carmela Dyer.

10. Estimate approved by: C. G. Nuckols (for James L. Blum, Assistant Director for Budget Analysis).

VIII. REGULATORY IMPACT STATEMENT

The Committee has determined that there will be minimal increase in regulatory burden of paperwork imposed by this bill.

The estimated number of individuals and businesses regulated by group or class are less than ten companies which manufacture smokeless tobacco products.

The estimated cost to the smokeless tobacco manufacturers for implementing the package requirements of this act is $2,500,000.

IX. SECTION-BY-SECTION ANALYSIS

This bill provides that the Act may be cited as the "Comprehensive Smokeless Tobacco and Health Education Act of 1985."

Section 2 of the bill directs the Secretary of Health and Human Services to establish and carry out a program to inform the public of any changes to human health resulting from the use of smokeless tobacco products. To accomplish this, the Secretary shall:

(A) develop educational programs and materials and public service announcements on the dangers to human health from smokeless tobacco use;

(B) make appropriate programs, materials, and announcements available to States, local governments, school systems, and other entities;

(C) conduct and support research on the effect of smokeless tobacco on human health; and

(D) collect, analyze, and disseminate information and studies on smokeless tobacco and health.

In developing programs, materials, and announcements, the Secretary shall consult with the Secretary of Education, medical and

public health entities, consumer groups, representatives of smokeless tobacco product manufacturers, and other appropriate entities.

Section 2 also authorizes the Secretary to provide technical assistance to States to assist them in the development of educational programs and materials and public service announcements on the dangers to human health from smokeless tobacco use.

Section 3 of the bill requires the Secretary of HHS to transmit to Congress not later than January 1, 1987, and biennially thereafter, a report containing:

(1) a description of the effects of health education efforts on the use of smokeless tobacco products;

(2) a description of the use by the public of smokeless tobacco products;

(3) an evaluation of the health effect of smokeless tobacco products and an identification of areas appropriate for futher research; and

(4) recommendations for appropriate legislation and administrative action.

Section 4 of the bill makes it unlawful for any person to knowingly manufacture, package, or import for sale or distribution within the United States any smokeless tobacco product unless the product package bears one of the following statements:

WARNING: THIS PRODUCT MAY CAUSE MOUTH CANCER;

WARNING: THIS PRODUCT MAY CAUSE GUM DISEASE AND TOOTH LOSS; or

WARNING: THIS PRODUCT IS NOT A SAFE ALTERNATIVE TO CIGARETTES.

The bill requires that the labeling statement appear in a conspicuous and prominent location on each smokeless tobacco product package, and in a conspicuous format, and in conspicuous and legible type in contrast with all other printed material on the package. The required statements must be randomly displayed in each twelve-month period in as equal a number of times as is possible, and be randomly distributed in all parts of the U.S. in which the product is marketed.

Section 4 requires each manufacturer, packager, or importer of a smokeless tobacco product to submit a plan to the Federal Trade Commission specifying the method to be used to display and distribute the required statements in accordance with this Act. The FTC is required to approve such a plan submitted by a manufacturer, packager, or importer if the plan provides for the display and distribution of the required statements on smokeless tobacco product packages in a manner which complies with this Act and with guidelines promulgated under section 6 below, and is required to disapprove any plan it determines fails to comply.

The requirements of this section and section 5 below do not apply to a distributor or a retailer of any smokeless tobacco product which does not manufacture, package, or import smokeless tobacco products for sale or distribution within the U.S.

Section 5 of the bill makes it unlawful for any manufacturer, packager, or importer of a smokeless tobacco product to knowingly advertise or cause to advertise in the U.S. a smokeless tobacco

product unless the advertisement bears one of the statements required in section 4 above. This section requires that each of the three statements be rotated every four months in an alternating sequence in advertisements for each brand of a smokeless tobacco product, in accordance with a method prescribed by the FTC. In the case of a printed advertisement, one of the statements shall appear in a conspicuous and prominent location and a conspicuous format, and in conspicuous and legible type in contrast with all other printed material in the advertisement. In the case of a radio or television advertisement, one of the statements shall be read once during the advertisement.

Each manufacturer, packager, or importer of a smokeless tobacco product is required to submit a plan to the FTC specifying the method to be used to rotate, display, and distribute the required statements in advertisements of smokeless tobacco products in a manner which complies with this Act and with the guidelines or rules promulgated under section 6 below. The FTC is required to approve a plan submitted by a manufacturer, packager, or importer if the plan provides for the rotation, display, and distribution of the required statements on each advertisement of a smokeless tobacco product in a manner which complies with this Act and the guidelines promulgated under section 6 below, and is required to disapprove any plan it determines fails to comply.

Section 6 of the bill requires the FTC to promulgate and periodically revise such regulations and guidelines as may be required to implement the warning statement and advertising requirements of the Act. Within 180 days after the enactment of this Act, the FTC is required to promulgate guidelines on the display, format and distribution of the required statement on smokeless tobacco product packages, and the rotation, display, format and distribution of the required statement on smokeless tobacco advertisements.

Section 7 of the bill requires each person who manufactures, packages, or imports smokeless tobacco products to provide the Secretary annually with:

> (A) a list of the ingredients added to tobacco in the manufacture of such products which does not identify the company which used the ingredients or the brand of smokeless tobacco which contains the ingredients; and
>
> (B) a specification of the quantity of nicotine contained in each such product.

The person or group of persons so required may designate an individual or entity to provide such information.

The Secretary is required to transmit to the Congress, at appropriate times, a report based on the ingredient information including:

> (A) a summary of research activities and proposed research activities on the health effects of ingredients added in the manufacture of smokeless tobacco products and the findings of such research;
>
> (B) information on any such ingredient which the Secretary's judgment poses a health risk to users of smokeless tobacco; and
>
> (C) any other information the Secretary determines to be in the public interest.

Section 7 requires that any information on ingredients provided to the Secretary shall be treated as trade secret or confidential information subject to section 552(b)(4) of title 5, U.S. Code, and section 1905 of title 18, U.S. Code, and shall not be revealed to any person other than those authorized by the Secretary in carrying out their official duties under this section. This section does not authorize the withholding of ingredient information provided under the section from any duly authorized subcommittee or committee of the Congress. If a subcommittee or committee requests the Secretary to provide it such information, the Secretary is required to make the information available to the subcommittee or committee and, at the same time, to notify in writing the person who provided the information of the request.

The Secretary is required to establish written procedures to assure the confidentiality of information provided under this section, including the designation of a duly authorized agent to serve as custodian. The agent is required to take physical possession of the information and, when it is not in use by a person authorized to have access, to store it in a locked cabinet or file; and to maintain a complete record of any person who inspects or uses the information. These procedures shall require that any person permitted access to the information must be instructed in writing not to disclose the information to anyone who is not entitled to have access.

Section 8 of the bill requires that any person who is found to violate any provision of this Act shall be guilty of a misdemeanor and on conviction be subject to a fine of not more than $10,000.

Section 9 of the bill invests the district courts of the U.S. with jurisdiction for cause shown, to prevent and restrain violation of this legislation upon application of the FTC or the Attorney General of the U.S. acting through U.S. attorneys in their districts.

Section 10 of the bill preempts any Federal agency or State or local law or regulation from requiring a statement related to the use of smokeless tobacco products and health other than the statement required by this Act to appear on any package or in any advertisement of a smokeless tobacco product.

Section 11 of the bill requires the Surgeon General of the U.S., after the Advisory Committee on the Health Consequences of Using Smokeless Tobacco completes its study and report, to review the findings and conclusions of the study. After the completion of the review, the Surgeon General is required, in consultation with the FTC, to recommend to the Congress appropriate revisions to the statements required in section 4 of this Act. Such recommendations shall be based on the findings and conclusions of the study.

Section 12 of the bill defines for the purposes of this Act the following terms:

(1) "package" means a pack, box, carton, can, or any other container of any kind in which smokeless tobacco is offered for sale, sold, or otherwise distributed to consumers;

(2) "person" has the same meaning as in section 3(5) of the Federal Cigarette Labeling and Advertising Act;

(3) "Secretary" means the Secretary of HHS;

(4) "smokeless tobacco" means any finely cut, ground, powdered, or leaf tobacco that is intended to be placed in the oral cavity; and

(5) "United States" has the same meaning as in section 3(3) of the Federal Cigarette Labeling and Advertising Act.

Section 13 of the bill states that the Act shall take effect one year after the date of enactment, except that sections 2, 3, 4(a), 5(a), and 6 which take effect on the date of enactment. Manufacturers, packagers, and importers may submit a plan to the FTC any time after enactment. The enforcement provisions requiring warning labels on packages and advertisements takes effect one year after enactment.

X. CHANGES IN EXISTING LAW

This legislation does not affect any existing law.

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